

# **Contract and Grant Manual**

## **ENVIRONMENTAL HEALTH AND SAFETY**

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### **3-100 INTRODUCTION**

This Chapter describes the University's environmental health and safety policies and procedures as they relate to the University's contract and grant administration. The University has established administrative procedures to comply with applicable State and federal environmental health and safety regulations. Most of these University procedures are in response to external requirements. These external requirements are outlined in the back of this Chapter.

### **3-200 UNIVERSITY POLICY ON HEALTH, SAFETY AND THE ENVIRONMENT**

The [University Policy on Management of Health, Safety and the Environment](#) sets forth the University's policy, standards, and guiding principles on health, safety and the environment. It provides a description of the University's integrated health, safety and environmental management system and states the University's commitment to comply with all applicable federal and State environmental health and safety rules and regulations.

#### *3-210 COMPLIANCE WITH APPLICABLE GOVERNMENT REGULATIONS*

The University must consider all applicable State and federal laws and regulations as well as other pertinent information concerned with the health and safety of employees and the protection of the environment. Specifically, the University Policy states:

The University of California is committed to achieving excellence in providing a healthy and safe working environment, and to supporting environmentally sound practices in the conduct of University activities. It is University policy to comply with all applicable health, safety, and environmental protection laws, regulations and requirements.

In complying with these various regulations, the University may issue its own policies and procedures and set up internal University committees to oversee their implementation.

#### *3-220 RESPONSIBILITY FOR COMPLIANCE*

As required by Title 8, California Code of Regulations, Section 3203, and in support of the University Policy on Management of Health, Safety, and the Environment, each campus is required to have a written Injury and Illness Prevention Program (IIPP) which identifies the person or persons with authority and responsibility for implementing the campus' health, safety, and environmental program. In most cases the Chancellor is identified as person responsible for ensuring that the policy is implemented; however, those in management positions, including Principal Investigators, are responsible for implementing the IIPP in their facilities within their respective jurisdiction. This responsibility includes ensuring that appropriate health and safety training is provided to employees within their facility.

The ["Guiding Principles to Implement the University of California Policy on Health, Safety and the Environment"](#) states that

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## 2. Management Responsibility for Safety and the Environment” that

University employees who direct the activities of other individuals are responsible for protecting faculty, staff, students, visitors, the public and the environment, and for adhering to this policy. Accountability should be addressed in job descriptions and performance evaluations, and in contracts.

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## 6. Identification of Safety and Environmental Standards and Requirements

Before a member of the University community conducts an activity which has potential adverse implications for health, safety or the environment, a responsible party must evaluate the associated hazards and environmental impacts and identify the appropriate set of protective safety and environmental requirements to assure that faculty, staff, students, visitors, members of the public, and the environment are protected from adverse affects. The principal responsibility for such an evaluation resides with employees and supervisors. The campus EH&S offices will provide assistance and consultation to identify requirements, controls, and their implementation.

The [Academic Personnel Manual, APM-245](#), Department Chairs, reiterates this administrative duty of Department Chairs (or equivalent officers) "to be responsible for departmental observance of proper health and safety regulations, in coordination with the campus health and safety officer." ([APM-245, Appendix A.](#))

Environment, Health and Safety Offices support this policy implementation by assisting managers/supervisors and Principal Investigators in identifying hazards and providing employee safety training programs. However, EH&S Offices support campus departments, but do not have the line authority to manage the safety programs in each department.

With regard to extramurally sponsored projects, Chancellors and Vice Presidents are responsible for ensuring that all matters of environmental health and safety have been considered and agency requirements are met before approving or recommending solicitations for contract or grant research, training or public service and that provisions for safe operation under the proposed programs have been or will be made.

Several University offices are responsible for review and implementation of environmental health and safety regulations and procedures. They advise faculty and staff regarding compliance with these procedures. These offices include: Environmental Health and Safety, Facilities Management, Risk Management, and Materiel Management. The role of each of these offices is discussed in further detail below in the sections which cover their respective areas.

### *3-230 CONTRACTS AND GRANTS OFFICERS' GENERAL RESPONSIBILITIES*

The general responsibility of Contracts and Grants Officers concerning environmental health and safety is to coordinate proposal or award review with the campus Environmental Health and Safety Office (EH& S) or other campus offices as applicable. Contracts and Grants Officers also sign clean air and water certifications. ([See Section 3-820.](#))

### **3-300 THE CALIFORNIA ENVIRONMENTAL QUALITY ACT (CEQA)**

The quality of the environment in California is protected by the [California Environmental Quality Act \(CEQA\)](#). (See [External Requirements 3-S01](#).) This Act was patterned after the [National Environmental Policy Act](#) (NEPA). (See [External Requirements 3-F01](#).)

CEQA requires that all State and public agencies, including the University, regulate their activities in a manner that gives major consideration to preventing environmental damage. The Act further requires that all State agencies prepare and certify the completion of an [Environmental Impact Report \(EIR\)](#) on any proposed project which may have a significant effect on the environment and that they adopt procedures which implement this Act and are consistent with the State CEQA Guidelines.

### *3-310 UNIVERSITY IMPLEMENTATION OF CEQA*

The [Regents' Policy on Approval of Design, Long Range Development Plans, and the Administration of the California Environmental Quality Act](#) states that the President "has the responsibility for the administration of the University's compliance with the California Environmental Quality Act." This [authority has been delegated](#) to the [Executive Vice President – Business Operations](#). The [Budget and Capital Resources Department](#) within Office of the President (OP) Business Operations is over: Capital Planning; Design and Construction; Facilities Management Services; Physical and Environmental Planning; Operating Budget; and Real Estate Services Group. [Physical and Environmental Planning](#) publishes [CEQA Compliance & Planning](#) including the [University CEQA Handbook](#) on its website.

The Physical and Environmental Planning unit provides guidance and reporting to The Regents on University land use and site planning, long range development plans, CEQA compliance, and environmental documents for all ten UC campuses, medical centers, and other university facilities. The campus Facilities Management or Planning Office is responsible for completing the Initial Study or the Environmental Impact Report required by CEQA for a project which is not exempt or categorically exempt from CEQA. (See Section 3-330 below.)

### *3-320 APPLICABILITY OF UNIVERSITY PROCEDURES FOR IMPLEMENTATION OF CEQA*

The [University CEQA Handbook](#) states that CEQA applies to:

University Long Range Development Plans and other University planning activities. A “Long Range Development Plan” is defined as a physical development and land use plan to meet the academic and institutional objectives for a particular campus or medical center of public higher education.

All “discretionary projects.” The term *discretionary* refers to situations in which a governmental agency can exercise its judgment in deciding whether and how to approve or carry out a project. The term *project* refers to the whole of an action that has the potential, directly or ultimately, to result in a physical change to the environment.

For the University of California, typical projects that could have a significant effect on the environment include capital construction projects, LRDPs, leases, acquisition of property, substantial changes in the use of facilities, and series of actions such as seismic renovation or asbestos removal. Real estate transactions such as leases and acquisitions of property may be considered projects that could have a significant effect on the environment.

CEQA does not apply to:

Projects which have [Statutory](#) or [Categorical Exemptions](#) such as anything specifically exempted by State law including but not limited to emergency projects, rejected projects, feasibility and planning studies, and ministerial projects.

Continuing administrative or maintenance activities, such as purchases for supplies, personnel-related actions, emergency repairs to public service facilities, general policy and procedure making (except as they are applied to specific instances covered above.)

Basic research projects handled by Contracts and Grants Offices rarely require any action under CEQA. As they usually have no significant impact on the environment, they are considered "Categorically Exempt" under the CEQA procedures. (See Section 3-330 below.)

### 3-330 COMPLIANCE WITH UNIVERSITY PROCEDURES FOR IMPLEMENTATION OF CEQA

Any University project, as defined in Section 3-320, which has "the potential for resulting in a physical change in the environment" must be classified as to its environmental impact. Projects requiring Office of the President consideration must be classified by the responsible administrative unit, usually the campus Facilities Management or Planning Office, at the time they are first proposed to the Office of the President for concurrence in funding, planning, development, or construction. The campus administrative unit submits an Environmental Impact Classification Form to the Office of the President for concurrence. For projects not requiring Office of the President consideration, such as minor capital projects funded from sources available to the responsible campus administrative unit, and all basic research projects which may need to be approved by the responsible campus administrative unit the administrative unit must classify them before it grants final project approval.

The following classifications are used:

1. *Exempt from CEQA* - if it can be seen with certainty that there is no possibility that the project may have a significant effect on the environment.
2. *Categorically Exempt* - if the project is included within the list of classes which have been determined to have no significant effect on the environment.
3. *Initial Study* - if the project is not exempt from CEQA or categorically exempt, and may have a significant effect on the environment.
4. *Environmental Impact Report* - if the project may, is likely to, or clearly will have a significant effect on the environment.

Basic research projects are usually considered to be in classification II. Categorically Exempt, under Class 6 of that classification. Class 6, Information Collection, is defined as follows:

Class 6 consists of basic data collection, research, experimental management, and resource evaluation activities which do not have a significant effect on the environment. These may be for strictly information-gathering purposes or as part of a study leading to an action which has not yet been approved, adopted, or funded.

However, a research project is not categorically exempt if there is a reasonable possibility that it may have a significant effect on the environment. Contracts and Grants Officers may contact their campus Facilities Management or Planning Office if there is a question about a research project being categorically exempt.

### **3-400 UNIVERSITY POLICY AND RESPONSIBILITIES FOR BIOHAZARDS AND RECOMBINANT DNA**

The University has not issued a university-wide policy on the use of biohazards and carcinogens. However, in accordance with the University Policy on Health, Safety and the Environment ([Section 3-200](#)), the University follows applicable State and federal guidelines and regulations covering biohazards, carcinogens, select agents and toxins. These guidelines and regulations are implemented by the campus or Laboratory Environmental Health and Safety Office and Institutional Biosafety Committees.

#### **3-410 RESPONSIBILITIES OF THE ENVIRONMENTAL HEALTH AND SAFETY OFFICE FOR RECOMBINANT DNA, BIOHAZARDS AND CARCINOGENS**

Each campus or Laboratory Environmental Health and Safety Office (EH&S) is responsible for monitoring and assisting departments and individuals who use hazardous materials to comply with University procedures and relevant government regulations. EH&S is responsible for implementing the [National Institute of Health \(NIH\) Guidelines for Research Involving Recombinant DNA \(rDNA\) Molecules](#), the Centers for Disease Control (CDC) [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\)](#) and CDC regulations on “Select

Agents and Toxins” at [42 CFR 73](#), the Department of Agriculture regulations on “Possession, Use, and Transfer of Select Agents and Toxins,” at [7 CFR 331](#) and [9 CFR 121](#), and other guidelines listed below in [Sections 3-450 to 3-470](#) for research using biohazardous and carcinogenic materials and for advising researchers and students regarding compliance with these guidelines. In cases where the Department of Energy (DOE) has issued Orders covering any of these areas, the Lawrence Berkeley National Laboratory (LBNL) generally follows these DOE Orders. Where there are no DOE Orders, LBNL follows applicable federal regulations.

EH& S inspects laboratories where proposed research using biohazards or carcinogens would take place. In response to the Contracts and Grants Office proposal cover sheets which indicate laboratories that may be used for research with biohazards or carcinogens, EH& S staff reviews and approves the facilities for the proposed research. It advises the Principal Investigator on safe laboratory procedures and materials required. On some campuses, EH& S reviews the entire proposal to assure that laboratory protocols and materials are in accordance with applicable guidelines and regulations.

The campus Institutional Biosafety Committee, [required by the NIH Guidelines](#), approves EH&S policies and reviews higher risk research proposals. The Biological Safety Officer described in [the NIH Guidelines](#) is an administrative staff member of EH&S. Proposals for higher biosafety level research are presented to the campus Institutional Biosafety Committee via EH&S for review and approval. (See [Section 3-452](#).)

### *3-420 ROLE OF THE CONTRACTS AND GRANTS OFFICE*

Generally, the Contracts and Grants Office receives a proposal with a cover sheet which indicates if biohazards, carcinogens or recombinant DNA (rDNA) would be involved in the research. If the Principal Investigator (PI) indicates they would be, this cover sheet is forwarded to the Environmental Health and Safety Office. (On some campuses, EH&S reviews the entire proposal.)

The Principal Investigator generally submits a proposal requiring the campus Institutional Biosafety Committee review and approval directly to that committee through EH&S prior to sending it to the Contracts and Grants Office.

When the Office of Environmental Health and Safety receives the proposal or the C&G proposal cover sheet, it can begin the review and approval procedures necessary. However, if a laboratory needs modifications, safety instruments, or other requirements to be approved for the proposed research, the Principal Investigator should be aware of the costs incurred by such required renovations and modifications when determining the proposed research budget. If the PI does not know whether a proposed laboratory will meet EH&S requirements, consulting with campus EH& S staff before determining the proposal budget would let the PI know if the proposed research would involve laboratory renovation or modification expenditures.

If a proposal using recombinant DNA contains proprietary data and potentially patentable concepts, a Proprietary Data legend should be included by the Principal Investigator. This legend would specify the paragraphs and pages which contain potentially patentable concepts

and proprietary data. Supplemental information on this subject is disseminated via [Contract and Grant Memo79-33](#).

### 3-430 *RESPONSIBILITIES OF PURCHASING/MATERIEL MANAGEMENT*

Each campus has developed its own purchasing policies and guidelines for procuring these regulated materials. These campus policies are governed by the campus Biosafety Committee. For specific requirements, campus investigators should contact the campus Biosafety Officer in the campus EH&S Office.

### 3-440 *BIOHAZARDS*

Biohazards, as the term is used in the context of scientific research, are microorganisms, including recombinant DNA (rDNA) molecules, which are commonly accepted as posing a hazard to human health or the environment. Biohazards used in research include pathogenic bacteria, fungi, parasites, protozoans, viruses, oncogenic viruses, rDNA, and plant and animal toxins. University practices regarding these biohazards are discussed in the following [sections 3-450 through 3-480](#).

### 3-450 *RECOMBINANT DNA*

The University follows the [National Institute of Health \(NIH\) Guidelines for Research Involving Recombinant DNA \(rDNA\) Molecules](#) for all research involving recombinant DNA molecules (rDNA) for which the University is responsible, not just for research funded by NIH. As the Guidelines state: “All non-NIH funded projects involving recombinant DNA techniques conducted at or sponsored by an institution that receives NIH funds for projects involving such techniques must comply with the *NIH Guidelines*.”

### 3-451 *NIH Guidelines*

The *NIH Guidelines for Research Involving Recombinant DNA Molecules* govern the conduct of NIH supported research in recombinant DNA molecules. They establish carefully controlled conditions for the conduct of experiments involving:

- (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or
- (ii) molecules that result from the replication of those described in (i) above.

The *NIH Guidelines* assign rDNA research to [one of four levels of biosafety](#), or levels of physical containment, BL1 through BL4, based on the potential hazard posed by each experiment. Each rDNA experiment is subject to a review and approval procedure, depending on its determined biosafety level.

### 3-452 Responsibilities of the University under the NIH Guidelines

The University is responsible for ensuring that all recombinant DNA research is carried out in [full conformity with the provisions of the NIH Guidelines](#). (See External Requirements [3-F02](#).) In order to fulfill this responsibility, the University shall:

#### 1. *Establish and Implement Policies*

Establish and implement policies that provide for the safe conduct of recombinant DNA research and that ensure compliance with the Guidelines. The University may establish additional procedures, as deemed necessary.

#### 2. *Establish an Institutional Biosafety Committee (IBC)*

Establish an Institutional Biosafety Committee (IBC) that meets the membership and procedure requirements listed in the *NIH Guidelines* and carries out the functions of reviewing rDNA research proposals and activities.

#### 3. *Appoint a Biological Safety Officer (BSO)*

If the University is engaged in recombinant DNA research at the BL3 or BL4 containment level, it shall appoint a BSO who shall be a member of the IBC and carry out the duties specified in *NIH Guidelines*.

### 3-453 California Environmental Quality Act (CEQA) Applicability to Recombinant DNA Research Activities

CEQA requires the preparation of an Environmental Impact Report (EIR) on any project which may have a significant effect on the environment. The decision as to whether an EIR is required for a research project involving recombinant DNA can only be made after an analysis of the proposed experiment and the facility in which the experiment is to take place. For example, DNA research conducted under approved contained laboratory conditions may not require an EIR, while any proposed rDNA research outside the laboratory setting may need review under the University Procedures for Implementation of CEQA. (See [Sections 3-310 through 3-330](#).)

### 3-460 ETIOLOGIC AGENTS, ONCOGENIC VIRUSES, SELECT AGENTS AND TOXINS

Etiologic agents are infectious agents such as viruses, bacteria, or fungi which cause diseases. Oncogenic viruses are tumor causing viruses. Research using these agents must be conducted under proper laboratory biosafety practices. The Centers for Disease Control (CDC) has published [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\)](#) for working with infectious agents in various laboratory settings.

Requirements for importation of etiologic agents are available from the CDC [Etiologic Agent Import Permit Program \(EAIPP\)](#). This website includes links to regulations and guidance on:

- International shipment of human pathogens and related materials ([World Health Organization Guidance on Regulations for the Transport of Infectious Substances](#));
- Department of Transportation regulations for interstate shipping of hazardous materials ([49 CFR Part 173](#));
- [IATA Dangerous Goods Regulations \(International Air Transport Association\)](#);
- [Department of Agriculture \(USDA\), Animal and Plant Health Inspection Service \(APHIS\) permits](#) required for infectious agents of livestock and biological materials containing animal material; and
- Export of a wide variety of etiologic agents of human, plant, and animal diseases requiring a [license from the Department of Commerce](#).

Additional requirements for using select agents and toxins on the CDC or USDA lists of select agents and toxins are published in the Code of Federal Regulations (CFR) at [42 CFR 73](#), CDC regulations on “Select Agents and Toxins,” and at [7 CFR 331](#) and [9 CFR 121](#), the Department of Agriculture regulations on “Possession, Use, and Transfer of Select Agents and Toxins.”

In addition, individuals wishing to import select agents and toxins must be registered with CDC's Select Agent Program in accordance with [42 CFR Part 73](#) (Select Agents and Toxins) for the select agent(s) and toxin(s) listed on the import permit application. Approval to ship select agents or toxins under the import permit must be granted before shipping. Additional information can be found on the USDA APHIS/CDC [National Select Agent Registry website](#).

### 3-461 Centers for Disease Control Biosafety Levels

The [four CDC biosafety levels for research using etiologic agents](#) and oncogenic viruses described in the [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\)](#) parallel those in the *NIH Guidelines* for research involving recombinant DNA. The CDC guidelines are advisory and do not mandate biosafety committee review of research proposals. Most campuses have, however, instituted review processes for research involving etiologic agents. (See External Requirements [3-F03](#).) Also see the National Research Council publication, [Prudent Practices in the Laboratory: Handling and Management of Chemical Hazards](#).

### 3-470 CARCINOGENS

The uses of certain chemical carcinogens are regulated in [California Code of Regulations \(CCR\) Title 8 Industrial Relations Section 5203 et seq.](#) The campus EH&S Office which oversees the use of carcinogens may add other hazardous, toxic or carcinogenic chemicals to the [list of cancer-causing substances](#) provided in this Code as well as in the California Labor Code, Section 9000 et. seq. as it deems necessary. (See External Requirements [3-S03](#).) LBNL follows DOE Order [440.1B, Worker Protection Program for DOE \(Including the National Nuclear Security Administration\) Federal Employees](#), when dealing with carcinogens.

### **3-500 RADIATION**

The use of radiation is the responsibility of the Radiation Safety Unit of the Environmental Health and Safety Office and the campus Radiation Safety Committee. Campuses with nuclear reactors also have a Reactor Supervisor and a Reactor Operations Committee responsible for use of the reactor.

In California, the [State Health and Safety Code](#) governing use of radiation supersedes federal regulations except when such use involves nuclear reactors, Department of Energy contracts, or the use of radioactive material on federal property. In these cases, the [Nuclear Regulatory Commission regulations](#) (10 CFR Chapter 1) govern the licensing and use of radioactive materials and radiation-producing machines. (See [External Requirements 3-F11](#).) In addition, the [Food and Drug Administration issues regulations](#) (21 CFR Chapter 1) which govern radiation emissions from electronic products. (See [External Requirements 3-F12](#).)

The California Code governing radiation control is set forth in [CCR Title 17, Public Health Section 30100](#). It is based on agreement with the Nuclear Regulatory Commission, subject to the provisions of [10 CFR Part 150](#). In general, these regulations require the licensing or registration of anyone possessing or using radioactive materials or radiation-producing machines. The California State Department of Public Health, [Radiologic Health Branch](#), licenses each campus for possession and use of radioactive materials and radiation-producing machines. (See External Requirements [3-S04](#).)

Use of radiation at LBNL follows DOE Order [440.1B](#).

#### **3-510 RESPONSIBILITIES OF EH&S AND THE RADIATION SAFETY COMMITTEE**

The Radiation Safety Committee establishes policies which implement federal and State regulations and statutes pertaining to the use of radioactive materials and ionizing radiation-producing machines. It authorizes the use of ionizing radiation on campus. Each campus with a radioactive materials license must have a Radiation Safety Officer (RSO) who, in addition to advising on regulatory requirements, provides technical staff to the Radiation Safety Committee.

EH&S reviews proposals involving radiation and, after approval by the Radiation Safety Committee, issues Radiation Use Authorizations (RUA) to the Principal Investigators. A valid RUA must be in effect prior to ordering radioactive material. Radioactive material shipments are routed through EH&S. EH&S is responsible for transportation and disposal of radioactive wastes and the training of employees in all aspects of radiation safety. It inspects and monitors radiation uses and electronic product radiation safety to assure compliance with appropriate State and federal codes and regulations.

### 3-511 Nuclear Reactor Supervision

The Reactor Operations Committee and Reactor Supervisor are responsible for establishing policies which implement federal regulations governing the use of a nuclear reactor. They must review and approve proposed experiments which would involve the use of the reactor.

### 3-520 ROLE OF THE CONTRACTS AND GRANTS OFFICE

The cover sheet or approval form which accompanies a proposal from a Principal Investigator to the Contracts and Grants Office asks for the application or RUA number of the Investigator if radiation is involved in the research proposed. If such authorization has not been obtained or applied for, the Investigator is referred to EH&S. Generally, Principal Investigators apply for or have an RUA before submitting a proposal to the Contracts and Grants Office.

### 3-600 CONTROLLED SUBSTANCES - DRUGS AND NARCOTICS

The federal ([21 CFR Part 1300 et seq.](#)) and State of California ([Health and Safety Code 11100 et seq.](#)) Uniform Controlled Substances Acts require the University to have specific procedures for the acquisition and use of controlled substances, as defined in these Acts.

#### 3-610 UNIVERSITY CONTROLLED SUBSTANCES PROGRAM - BUSINESS AND FINANCE BULLETIN BUS-50

The University procedures for the acquisition and use of controlled substances are established in *Business and Finance Bulletin* [BUS-50, Controlled Substances Program](#). The purpose of this Bulletin is to implement the requirements of the federal and State Uniform Controlled Substances Acts. It sets forth the roles and responsibilities for establishing and maintaining University's Controlled Substances Program.

In accordance with BUS-50, the Chancellor or Laboratory Director is responsible for designating, in writing, a Responsible Official to establish and oversee the campus or Laboratory program. The Responsible Official's designee (such as personnel from Environment, Health and Safety) charged with implementing and managing the Controlled Substances Program on a day-to-day basis.

Campus and LBNL Material Managers or Purchasing Officers are responsible for procuring controlled substances, registration, order forms, and reporting requirements in compliance with the federal and State Uniform Controlled Substances Acts. (See External Requirements [3-F04](#) and [3-S05](#).) BUS-50 sets forth the procedures for the campus Material Management and the Laboratory Purchasing Office to follow in order to register for the appropriate research classifications and to apply for the acquisition and use of controlled substances. *BUS-50* also sets forth the procedures for issuing orders for controlled substances, for effective controls against theft and diversion, and for maintaining records and inventories.

### *3-620 RESPONSIBILITIES OF PRINCIPAL INVESTIGATORS*

The Principal Investigator or Department Chair initiates and signs requisitions for controlled substances. For any [controlled substance on Schedule I, as defined by the Controlled Substances Acts](#) (see [External Requirements 3-F05](#)), the research protocol describing the project must be submitted to Materiel Management with the application. At the same time, a research proposal must be submitted to the [State Research Advisory Panel](#). (See [External Requirements 3-S05](#).) BUS-50 outlines the applicable laws and gives the definitions of the five Schedules of Controlled Substances and procedures for Principal Investigators to follow to apply to the State Research Advisory Panel and to acquire controlled substances.

If funds to support research are being sought from any federal, State or local granting agency, the Investigator should submit the proposal prior to or with the application to the State Research Advisory Panel. (See [External Requirements 3-S05](#) for further information on requirements of the State Research Advisory Panel.) In addition, if approval is needed from any other federal or State agency (see [Section 3-630](#)), the Investigator must apply for such approval and show evidence of it to the Materiel Manager.

Principal Investigators or laboratory employees (e.g. staff and/or students) who are authorized to possess or use Controlled Substances by the University or LBNL are responsible for complying with federal and State regulations, program requirements, and University/Laboratory policy governing the acquisition, use, storage, and disposition of controlled substances.

### *3-630 REQUIREMENTS OF OTHER FEDERAL AND STATE AGENCIES*

Approval is required from the federal Food and Drug Administration for interstate commerce of controlled substances and for human subject studies. (See C& G Manual [Chapter 18, Protection of Research Subjects](#).) The State Department of Justice, [Office of the Attorney General](#), is the cognizant office if intrastate commerce is involved.

### **3-700 HUMAN HEALTH AND SAFETY**

As required by [Title 8, Industrial Relations, California Code of Regulations Section 3203](#), “Injury and Illness Prevention Program,” and in support of the [University Policy on Management of Health, Safety, and the Environment](#), each campus is required to have a written Injury and Illness Prevention Program (IIPP) which identifies the person or persons with authority and responsibility for implementing the campus’ health, safety, and environmental program. In most cases, the Chancellor is identified as being responsible for ensuring that the policy is implemented. However, those in management positions, including Principal Investigators, are responsible for implementing the IIPP in their facilities within their respective jurisdiction. This responsibility includes ensuring that appropriate health and safety training is provided to employees within their facility.

### *3-710 RESPONSIBILITIES OF ENVIRONMENTAL HEALTH AND SAFETY OFFICES*

EH&S staff evaluate potential hazards and coordinate campus programs to prevent injuries and work-related illnesses at the University. They work with academic departments and administrative services to develop training, monitoring, and accident prevention programs. EH&S Offices

support the mission of the University by providing comprehensive environmental protection, occupational health, and industrial safety expertise to the entire University community. EH&S enables the research and educational processes through training and consultation, facilitating loss prevention programs, and providing a framework for workplace hazard analysis and control.

In addition to the areas discussed in Sections [3-410](#) and [3-510](#), EH&S concerns include: emergency planning; seismic, fire, office and industrial safety; asbestos; PCBs; pest management; sanitation; hazardous waste management; and diving safety.

### *3-720 RESPONSIBILITIES OF RISK SERVICES*

The President is [assigned the authority and responsibility](#) for coordination of the University Risk Management Program. The [OP Risk Services Office](#) is responsible for implementing the Risk Management Policy. In relation to environmental health and safety issues, the Risk Management Policy is to "eliminate or modify conditions and practices, whenever practical, which may cause loss."

The campus Risk Management Office is responsible for analyzing causes of personal injury and property damage. Risk Management staff collaborates with EH&S staff in developing insurance, security and prevention programs in such areas as industrial, seismic and fire safety. Such programs are aimed at minimizing risks and losses for the campus. Risk Services is also concerned with indemnity issues in regard to disposal of hazardous wastes. (See C & G Manual [Chapter 21, Risk Management](#).)

### *3-730 ROLE OF DEPARTMENT CHAIRPERSONS*

The Department Chairperson or equivalent officer is responsible for "departmental observance of proper health and safety regulations in coordination with the campus Health and Safety Officer" ([APM-245](#)). EH&S acts in an advisory capacity to the Departmental Chairperson and Principal Investigator, providing guidance on the implementation of regulations and the use of hazardous materials.

### *3-740 APPLICABLE STATE AND FEDERAL REGULATIONS*

The two major laws which cover the health and safety of workers are the [federal](#) (29 CFR Chapter XVII) and [State \(Labor Code Section 6300\) Occupational Safety and Health Acts](#). (See External Requirements [3-F05](#) and [3-S02](#).)

In addition to these major acts and the laws and regulations previously described in this chapter, the following federal and State laws covering worker health and safety are outlined under External Requirements:

Federal –

[Toxic Substances Control Act \(3-F06\)](#)

[Federal Food, Drug and Cosmetic Act \(3-F07\)](#)

[Federal Insecticide, Fungicide and Rodenticide Act \(3-F08\)](#)

[Resource Conservation and Recovery Act \(3-F12\)](#)

State -

[Occupational Carcinogens Control Act \(3-S03\)](#)

### **3-800 CERTIFICATIONS FOR CLEAN AIR AND WATER**

The Federal Clean Air Act ([42 USC 7401 et seq.](#)) and the Federal Water Pollution Control Act ([33 USC 1251 et seq.](#)) require federal awards to include certifications of compliance with these Acts. (See External Requirements [3-F09](#).) The certification states that the awardee and any facility to be used in performance of the agreement will comply with the standards of these regulations. No facility included in the [Federal Excluded Parties List](#) may be used in the performance of a federal or State contract or grant.

State of California [Government Code Section 4475 et. seq.](#) states that

No state agency shall enter into any contract for the purchase of supplies, equipment, or services from any person who is in violation of any order or resolution not subject to review promulgated by the State Air Resources Board or an air pollution control district, or is subject to a cease and desist order not subject to review issued pursuant to Section 13301 of the Water Code for violation of waste discharge requirements or discharge prohibitions, or is finally determined to be in violation of federal laws relating to air or water pollution.

The State contract or grant clause requires the contractor to certify that no portion of the work to be done will be performed at a facility which is in violation of any State or federal air or water pollution orders. (See External Requirements [3-S06](#).)

### **3-810 RESPONSIBILITIES OF MATERIEL MANAGEMENT - BUSINESS AND FINANCE BULLETIN, BUS-56**

Business and Finance Bulletin [BUS-56](#), *Materiel Management: Purchases from Entities Violating State or Federal Water or Air Pollution Laws*, sets forth the procedures for the University implementation of these laws. Materiel Managers are prohibited "from entering into contracts of \$10,000 or more for the purchase of supplies, equipment or services from any person entity who has been determined to be in violation of federal or State air or water pollution laws in violation of this statute." Where subcontracts are administered by campus Contract and Grant

Offices, those offices are responsible for confirming that a proposed subcontractor is not on the [Federal Excluded Parties List](#).

### 3-820 *ROLE OF CONTRACTS AND GRANTS OFFICERS*

Contracts and Grants Officers may sign federal contracts or lists of certifications and representations which include the clean air and water certifications. The signature certifies that the University does not use any facility in the performance of this proposed award which has been listed on the [Federal Excluded Parties List](#) as an EPA violating facility.

In State contracts, clean air and water compliance clauses are incorporated in the exhibits.

### 3-999 RELATED UNIVERSITY OF CALIFORNIA REFERENCES

[University Policy on Management of Health, Safety and the Environment](#)

[Academic Personnel Manual \(APM\) Section 245, Appendix A](#), “Duties of Department Chairpersons (or Equivalent Officers).”

[Presidential Delegation of Authority to Senior Vice President - Administration](#), “Implementation of California Environmental Quality Act.”

[University CEQA Handbook](#).

[Contract and Grant Memo No. 33-79](#), “Proprietary Data Legend for Protection of Sensitive Data Submitted in Research Proposals.”

*Business and Finance Bulletin* [BUS-50](#), “Controlled Substances Program.”

[University Risk Financing Policy](#)

[Presidential Delegation of Authority to Vice President](#) - Financial and Business Management, Risk Management Program,

*Business and Finance Bulletin* [BUS-56](#), “Material Management: Purchases from Entities Violating State or Federal Water or Air Pollution Laws.”

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### EXTERNAL REQUIREMENTS--FEDERAL

3-F01 [National Environmental Policy Act](#) of 1969 as Amended (PL 91-190 [42 USC §4321 et seq. as amended](#))

## IMPLEMENTING REGULATIONS

### [40 CFR Part 6](#)

#### PURPOSE

To establish a National Environmental Policy and Council on Environmental Quality. The Declaration of National Environmental Policy calls for federal government, in cooperation with state, local, public and private organizations, to use all means to foster and promote the general welfare, to create and maintain conditions under which humans and nature can exist in productive harmony, and to fulfill responsibility of each generation as trustees of the environment for future generations.

#### SUMMARY

These regulations require information on and coordination of federal projects and programs impacting the environment, including environmental impact statements, initial and use planning information, and review and public involvement. Federal agencies must include appropriate and careful consideration of all environmental effects of a proposed action.

#### APPLICABILITY

Regulations apply to federal agencies and all federal assistance programs. Environmental assessment must be prepared by grantee for each federally assisted project if it falls within categories required.

#### LEAD AGENCY

[Environmental Protection Agency](#)

[Council on Environmental Quality](#)

#### UNIVERSITY RESPONSIBILITY

In general, the University implements the National Environmental Policy Act, (NEPA) through compliance with the California Environmental Quality Act (CEQA). (See [3-S01](#)). However, there are circumstances under which Facilities Management prepares environmental impact documents under NEPA federal awards because a research project is determined to be categorically exempt under CEQA, but not excluded under NEPA.

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## **EXTERNAL REQUIREMENTS--FEDERAL**

3-F02 [National Institutes of Health \(NIH\) Guidelines for Research Involving Recombinant DNA \(rDNA\) Molecules](#)

### **IMPLEMENTING REGULATIONS**

[59 FR 34472](#) and amendments

### **PURPOSE**

To specify practices for constructing and handling recombinant DNA (rDNA) molecules and organisms and viruses containing recombinant DNA molecules.

### **SUMMARY**

Regulations establish four biosafety levels (BL) or levels of physical containment for classifying rDNA research, depending on the risk posed by the etiological agents to be used in the proposed research. These biosafety levels consist of combinations of laboratory practices, safety equipment, and laboratory facilities appropriate for the operations performed and the hazards posed by any proposed rDNA research. Agents assigned to biosafety level 4 (BL4) require the most stringent containment conditions. Those assigned to BL1 require the least stringent.

The regulations describe the guidelines for classifying rDNA experiments and their review procedures, and the membership requirements, functions and responsibilities of the Institutional Biosafety Committee (IBC), which reviews proposed rDNA research.

They require the institution to appoint a Biological Safety Officer (BSO) if it is engaged in rDNA research at the BL3 or BL4 containment level. The officer shall be a member of the IOB0RC. The duties of the BSO are described. They describe the responsibilities of Principal Investigator for compliance with the Guidelines and as well as the responsibilities of NIH.

### **APPLICABILITY**

Regulations are required for institutions receiving NIH funds for rDNA research and are voluntary for others.

### **LEAD AGENCY**

[National Institutes of Health](#)

### **UNIVERSITY RESPONSIBILITY**

Campuses appoint an Institutional Biosafety Committee (IBC) and a Biological Safety Officer (BSO) to implement the Guidelines. The BSO is a member of the IBC and a staff member of campus EH&S. EH&S is responsible for establishing and implementing policies that provide for

the safe conduct of rDNA research and ensure compliance with the Guidelines and establishing additional procedures as necessary.

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## **EXTERNAL REQUIREMENTS--FEDERAL**

### 3-F03 [Biosafety in Microbiological and Biomedical Laboratories](#)

#### **PURPOSE**

Recommends best practices for the safe conduct of work in biomedical and clinical laboratories from a biosafety perspective.

#### **SUMMARY**

This publication sets forth a code of practice for biosafety—the discipline addressing the safe handling and containment of infectious microorganisms and hazardous biological materials, including microbiological containment practices, safety equipment, and facility safeguards that protect laboratory workers, the environment, and the public from exposure to infectious microorganisms handled and stored in a laboratory that constitute biosafety levels 1-4.

#### **APPLICABILITY**

These guidelines are for research facilities using infectious microorganisms, hazardous biological materials and etiologic agents, select agents and toxins and are advisory from the Centers of Disease Control.

#### **LEAD AGENCY**

[Centers for Disease Control](#)

#### **UNIVERSITY RESPONSIBILITY**

EH&S Office reviews proposed research procedures and laboratory facilities for compliance with biosafety levels recommended. Some campuses require specific authorizations from EH&S for use of infectious microorganisms, hazardous biological materials and etiologic agents.

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## **EXTERNAL REQUIREMENTS--FEDERAL**

3-F04 Comprehensive Drug Abuse Prevention and Control Act of 1970  
Federal Controlled Substances Act ( [21 USC 801 et seq.](#))

### IMPLEMENTING REGULATIONS

[21 CFR Chapter 11](#)

#### PURPOSE

To provide increased research into and prevention of drug abuse and dependence, treatment, and rehabilitation. To strengthen existing law enforcement authority in the drug abuse field and to consolidate all federal marijuana, narcotics and dangerous drug laws.

This Act is designed to control the legitimate drug industry as well as to curtail the importation and distribution of illicit drugs throughout the United States.

#### SUMMARY

This Act provides funds for rehabilitation programs and research. The regulations set up controls, enforcement, penalties, and administration. They establish the schedules of controlled substances, restrictions, and registration classifications for their use.

#### *Schedules of Controlled Substances - Section 202*

The Act establishes five schedules of controlled substances, which classify drugs and narcotics based on abuse potential, and gives restrictions for obtaining and handling them. Schedule I lists those substances with the highest abuse potential and Schedule V names those with the lowest potential. A listing of the specific items in each schedule is published annually by the Drug Enforcement Administration under the title "Controlled Substances Inventory List." Further details about the Schedules are given in Appendix A of *Business and Finance Bulletin* [BUS-50](#).

#### *Registration Classifications*

The Federal Controlled Substances Act establishes registration classifications for the use of controlled substances. Application for the use of any scheduled substances must be in the specific registration classifications which apply to that institution.

#### APPLICABILITY

Any use of scheduled substances.

#### LEAD AGENCY

[Drug Enforcement Administration \(DEA\)](#)

## UNIVERSITY RESPONSIBILITY

Materiel Management must submit applications to DEA for use of controlled substances in Schedules I through V. These applications are for use in the specific registration classifications which apply to the University. They are:

1. Teaching Institution using Schedules II through V
2. Hospital/Clinic using Schedules II through V
3. Research in Schedule II through V
4. Research in Schedule I
5. Chemical Analysis distinct from research
6. Manufacture

Each campus Materiel Management or Laboratory Purchasing Office registers its campus with the DEA for the classifications which apply to its needs. (See [Section 3-610.](#)) Once a campus or laboratory is registered in a classification, it can acquire controlled substances from Schedules II through V for use in that classification. Materiel Management must control the acquisition and distribution of schedules substances.

A separate registration is required for each research project under Schedule I. The Principal Investigator initiates this application, which includes a description of the research protocol, and submits it to Materiel Management. (See *Business and Finance Bulletin* [BUS-50](#) for further detail.)

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## EXTERNAL REQUIREMENTS--FEDERAL

3-F05 Occupational Safety and Health Act ([29 USC 667 et seq.](#))

## IMPLEMENTING REGULATIONS

[29 CFR 1900](#)

## PURPOSE

To establish regulations for the workplace to assure that no employee will suffer diminished health as a result of working conditions. To set forth procedures for development of state plans, enforcement and reporting, and federal standards and penalties.

## SUMMARY

This Act establishes regulations to protect the health and safety of workers. The regulations set forth state planning for development and enforcement of state standards and procedures for inspections, citations, proposed penalties, and reporting injuries and illnesses. They list occupational health and safety standards for various work sectors and industries. The Act creates the [National Institutes for Occupational Safety and Health \(NIOSH\)](#), which conducts studies and makes recommendations. It creates a broad mechanism for protecting workers from workplace hazards and occupational exposure to hazardous chemicals in laboratories as well as blood borne pathogens.

## APPLICABILITY

States and interstate commerce industries.

## LEAD AGENCY

[Department of Labor](#)

## UNIVERSITY RESPONSIBILITY

EH& S is responsible for appropriate implementation of applicable State OSHA regulations, which are approved by Secretary of Labor in accordance with these federal regulations. (See [3-S02.](#))

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## EXTERNAL REQUIREMENTS--FEDERAL

3-F06 Toxic Substances Control Act of 1977 ([15 USC §2601-2629](#))

## IMPLEMENTING REGULATIONS

[40 CFR 700](#)

## PURPOSE

To regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances.

## SUMMARY

Sets forth conditions to test for possible health or environmental risk. Makes rules, procedures, and regulations. Provides for data collection, record keeping, and enforcement. Fills gaps in other environmental laws by authorizing the [Environmental Protection Agency \(EPA\)](#) to acquire

information on chemical substances in order to identify and evaluate potential hazards and then to regulate the production, use, distribution, and disposal of those substances.

#### APPLICABILITY

Consulting laboratories, contractors, and grantees performing studies to which these regulations apply. Applies to commodity and specialty chemicals made by biotechnology and microorganisms used in the environment.

#### LEAD AGENCY

EPA with rules issued by EPA and Treasury Department.

#### UNIVERSITY RESPONSIBILITY

[EH&S Office is responsible for implementing the regulations](#) under this law which include: proper handling, resting and storage of substances; equipment maintenance; records retention; and employee protection.

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#### **EXTERNAL REQUIREMENTS--FEDERAL**

3-F07 Federal Food, Drug and Cosmetic Act (FFDCA)

Amended by Medical Devices Amendments of 1976 ([21 USC 301 et seq.](#))

#### IMPLEMENTING REGULATIONS

[21 CFR Part 1](#)

#### PURPOSE

To regulate drugs, biologics, food, food additives, cosmetics, and tobacco products.

#### SUMMARY

These regulations establish good laboratory and manufacturing practices and require premarketing testing of certain products.

#### APPLICABILITY

Consulting laboratories, contractors, grantees, and manufacturers.

#### LEAD AGENCY

## [Food and Drug Administration](#)

### UNIVERSITY RESPONSIBILITY

The EH&S Office is responsible for implementing the safe laboratory practices required by the regulations under this law.

The Principal Investigator must apply for a permit from the Food and Drug Administration for work involving an experimental use stage of any product covered by these regulations.

Under the [Medical Devices Amendments](#), the Principal Investigator must apply to the Food and Drug Administration for an [Investigational Device Exemption](#) required to conduct clinical trials of a medical device.

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### **EXTERNAL REQUIREMENTS--FEDERAL**

3-F08 Federal Insecticide, Fungicide and Rodenticide ACT (FIFRA) ([7 USC 136 et seq.](#))

### IMPLEMENTING REGULATIONS

[40 CFR 150](#) et seq.

### PURPOSE

To regulate development, studies, manufacture, and use of biological pesticides, herbicides, microorganisms, or their chemical products.

### SUMMARY

These regulations prescribe good laboratory practices and manufacturing requirements. They require studies in support of applications for research or marketing permits for pesticides products regulated by EPA and assure the quality and integrity of data. They cover treatment of animals, handling, storage, and testing of substances, and require EPA review of pesticides.

### APPLICABILITY

Consulting laboratory, contractor, grantee or manufacturer.

### LEAD AGENCY

[EPA](#)

## UNIVERSITY RESPONSIBILITY

The EH&S Office is responsible for implementing safe laboratory practices. The Principal Investigator must apply to the EPA for the permits required for experimental use stages.

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## EXTERNAL REQUIREMENTS--FEDERAL

3-F09 Federal Water Pollution Control Act of 1972 (PL 92-500; [33 USC 1251 et seq.](#))

Clean Water Act as amended (PL 91-604, 84 Stat., 1707)

Clean Air Act of 1970 (PL 91-604); and Amendments (1974 - PL 93-319; 1977 95-95; [42 USC 7401 et seq.](#))

[Executive Order 11738](#), "Providing for Administration of the Clean Air Act and the Federal Water Pollution Control Act with Respect to Federal Contracts, Grants, or Loans"

## IMPLEMENTING REGULATIONS

[40 CFR Part 25](#)

(E.O. 11738 - 38 FR 25161, September 12, 1973)

## PURPOSE

The Clean Water Act calls for restoration and maintenance of the chemical, physical, and biological integrity of the nation's waters.

The Clean Air Act's purpose is to protect and enhance the quality of air resources to promote health and welfare. It initiates research and development on prevention and control of air pollution.

E.O. 11738 assures that each federal agency which awards grants, contracts or loans undertakes procurements and assistance activities in a manner that will result in effective enforcement of the Clean Air and Water Acts, by implementing Section 306 of the Air Act and 508 of the Water Act. (See below.)

## SUMMARY

The Water Act covers the elimination of discharge of pollutants; protects fish and wildlife; prohibits toxic pollutants; and assists in construction of water treatment plants and in the development of research and technology.

The Clean Air Act authorizes activities of research and development programs; proposes ambient air standards; and sets forth pollution enforcement procedures. States are required to maintain standards of air quality.

Sections 306 of the Air Act and 508 of the Water Act are virtually identical in scope and impact. Each section provides general environmental standards and administrative requirements for federal contracts and grants subject to the Clean Air and Federal Water Pollution Control Acts. Regulations issued pursuant to these sections by the [Environmental Protection Agency \(EPA\)](#) are set forth in a detailed code of enforcement and compliance standards. These regulations may be found at 40 CFR Part 25.

Under the EPA regulations, sanctions may be imposed upon offending facilities when they fail to comply with federal and state requirements and orders issued pursuant to the Acts. In such cases, EPA may initiate hearing procedures which may result in the placement of the facility on a "list of violating facilities". The consequence of such action is that listed facilities may not be awarded future grants or receive extensions of existing grants. In addition, existing grants may be terminated.

Exempted from the Acts; requirements are grants, subgrants, and contracts issued by grantees for less than \$100,000. In addition, grants to assist facilities in their compliance with environmental requirements are exempted. These exemptions do not apply to facilities whose prior violations of environmental requirements have resulted in criminal convictions under either of the above cited Acts.

## APPLICABILITY

Sections 306 of the Air Act and 508 of the Water Act specifically apply to federal contracts, grants, loans, and subcontracts greater than \$100,000. Other sections of these Acts apply to all activities engaged in, supported, funded, licensed, permitted, or approved by any federal department or agency.

## LEAD AGENCY

[EPA](#)

## UNIVERSITY RESPONSIBILITY

Under [BUS-56](#), *Material Management: Purchases from Entities Violating State or Federal Water or Air Pollution Laws*, Material Management is responsible for assuring that the University does not subcontract or purchase with federal money to any person or facility on the EPA list of facilities in violation of Sections 306-Air Act and 508-Water Act. Contracts and Grants Officers certify the University's compliance with these Acts. Where subcontracts are administered by campus Contract and Grant Offices, those offices are responsible for confirming that a proposed subcontractor is not on the [Federal Excluded Parties List](#).

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## **EXTERNAL REQUIREMENTS--FEDERAL**

3-F10 Atomic Energy Act of 1954, as amended ([42 USC §§2011 et seq](#))

Energy Reorganization Act of 1974, as amended ([42 USC §§5801 et seq](#))

### **IMPLEMENTING REGULATIONS**

#### [10 CFR Chapter 1](#)

#### **PURPOSE**

To foster research and development of atomic energy and nuclear material; to disseminate technical information and benefits of such research; and to promote peaceful and defense uses and international cooperation for common defense and security. To establish government control of possession, use, and production of atomic energy and nuclear material. To set up program administration.

#### **SUMMARY**

These regulations govern all aspects of the use of nuclear materials including licensing, procedures to access restricted data, procedures to access and control these materials, and human and environmental protection standards. They set forth reporting procedures, standards for manufacturing and transporting nuclear materials, standards for patent licenses, security approvals, and import and export procedures.

#### **APPLICABILITY**

Any person, institution, political entity, corporation, etc. which uses or manufactures nuclear materials except for those exempt under [10 CFR Part 150](#) as Agreement States.

#### **LEAD AGENCY**

[Nuclear Regulatory Commission](#)

#### **UNIVERSITY RESPONSIBILITY**

The EH&S Radiation Safety Officer (or the Reactor Supervisor, as appropriate) is responsible to implementing these regulations for licensing and use of nuclear material and radiation-producing machines when they involve Department of Energy contracts, nuclear reactors, or use on federal property. In other cases, the State Radiation Control Codes apply as California is an Agreement State under [10 CFR Part 150](#). (See External Requirements [3-S04](#).)

LBNL follows [DOE Order 5480.1A](#), Chapter XI, Requirements for Radiation Protection.

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## **EXTERNAL REQUIREMENTS--FEDERAL**

3-F11 Radiation Control for Health and Safety Act of 1968 ([21 USC 360](#))

### **IMPLEMENTING REGULATIONS**

[21 CFR 1000 et seq.](#)

### **PURPOSE**

To provide for the protection of the public health from radiation emissions from electronic products.

### **SUMMARY**

This Act develops and sets up administration for performance standards to control emissions from: ionizing radiation emitting products; microwave and radio frequency emitting products; laser light emitting products; sonic, infrasonic, and ultrasonic emitting products; and radiation emitting products. It supports public and private organization research and investigation into the effects and control of such emissions. The regulations establish requirements for notification by manufacturers of defects, repairs, or replacements. They set up controls for imported products and require codes for reporting listed electronic products and electronic product radiation warnings.

### **APPLICABILITY**

Manufacturers and users of such products.

### **LEAD AGENCY**

[Food and Drug Administration](#)

### **UNIVERSITY RESPONSIBILITY**

EH&S and the Radiation Safety Officer are responsible for implementing regulations with regard to the safe use of these products.

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## **EXTERNAL REQUIREMENTS--FEDERAL**

3-F12 Resource Conservation and Recovery Act of 1976 as amended ([42 USC 6901](#))

### **IMPLEMENTING REGULATIONS**

[40 CFR Part 239 et seq.](#)

## PURPOSE

To provide technical and financial assistance for the development of management plans, facilities for the recovery of energy and other resources from discarded materials, and for the safe disposal of discarded materials. To regulate the management of hazardous waste. To set up state and regional plans for solid and hazardous waste disposal management.

## SUMMARY

These regulations set forth guidelines for solid or hazardous waste disposal and management. They regulate handling, storage, treatment, transportation, and disposal of solid or hazardous wastes and facilities and identify and list hazardous wastes. They provide for employee protections against firings when the employee reports violations of these regulations.

## APPLICABILITY

Any user, manufacturer, or disposer of solid and hazardous wastes.

## LEAD AGENCY

[Environmental Protection Agency](#)

## UNIVERSITY RESPONSIBILITY

EH&S is responsible for implementing these regulations, providing guidance to departments on the safe disposal of wastes, protecting employees, facilities, and the environment.

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## EXTERNAL REQUIREMENTS--FEDERAL

3-F13 Agricultural Bioterrorism Protection Act of 2002 ([7 U.S.C. 8401](#))  
Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ([42 U.S.C. 262a; sections 201–204, 221 and 231](#))

## IMPLEMENTING REGULATIONS

[42 CFR 73](#); [7 CFR 331](#); [9 CFR 121](#)

## PURPOSE

Implements the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the Agricultural Bioterrorism Protection Act of 2002 which require restricted access to select agents and toxins.

## SUMMARY

Sets forth the requirements for possession, use, and transfer of select agents and toxins. Assesses security risks and provides security requirements for access to these agents and toxins. The biological agents and toxins listed in these parts have the potential to pose a severe threat to public health and safety, to animal health, or to animal products, or to plant health or plant products. Overlap select agents and toxins are subject to regulation by both CDC and APHIS.

## APPLICABILITY

Applies to any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

## LEAD AGENCY

[Centers for Disease Control](#) and Protection - [U.S. Department of Health and Human Services; Animal and Plant Health Inspection Services \(APHIS\)](#) – [U.S. Department of Agriculture](#)

## UNIVERSITY RESPONSIBILITY

Each campus has developed its own purchasing policies and guidelines for procuring these regulated materials. These campus policies are governed by the campus Biosafety Committee. For specific requirements, campus investigators should contact the campus Biosafety Officer in the campus EH&S Office.

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## EXTERNAL REQUIREMENTS--STATE

3-S01 California Environmental Quality Act (CEQA) ([Public Resources Code §§21000 et seq.](#))

## IMPLEMENTATION REGULATIONS

[California Code of Regulations \(CCR\)](#)

## PURPOSE

To maintain a high quality environment for the people of the State. To require all State and public agencies to ensure that their activities are carried out in the best manner to prevent environmental damage.

## SUMMARY

CEQA is patterned after the National Environmental Policy Act. CEQA requires all State and public agencies to regulate their activities to prevent environmental damage. Regulations must be consistent with the Act and comply with the State CEQA. All State agencies prepare and

certify the completion of an environmental impact report on any proposed project which may have a significant impact on the environment.

#### APPLICABILITY

State and public agencies.

#### LEAD AGENCY

[California Natural Resources Agency](#)

#### UNIVERSITY RESPONSIBILITY

The [policy adopted by The Regents](#), as required by CEQA, and the University's implementation of CEQA are set forth in the [UC CEQA Handbook](#). The campus Facilities Management or Planning Office is responsible for submitting environmental impact reports when required by the guidelines. (See [Sections 3-300 to 330](#).)

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### **EXTERNAL REQUIREMENTS--STATE**

3-S02 [California Occupational Safety and Health Act \(Labor Code §§ 6300 et seq.\)](#)

#### IMPLEMENTATION REGULATIONS

[California Code of Regulations Title 8 Industrial Relations Section 340 et seq.](#)

#### PURPOSE

To fulfill requirements of federal [Occupational Safety and Health Act](#) by establishing State standards and procedures to provide a safe and healthful place of employment. (See [3-F05](#) above.)

#### SUMMARY

This code sets forth State occupational health and safety standards which are approved by the Secretary of Labor. It contains detailed regulations and safety orders for safety in employment, worker safety, safety devices, and safeguards. It sets forth health standards, inspection and investigation procedures, and hazardous substances information and training requirements.

#### APPLICABILITY

Employers in California.

## LEAD AGENCY

[Division of Occupational Safety and Health--Department of Industrial Relations](#)

## UNIVERSITY RESPONSIBILITY

The EH&S Office interprets and assists managers/supervisors and Principal Investigators in the implementation these health and safety codes.

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## EXTERNAL REQUIREMENTS--STATE

3-S03 Occupational Carcinogens Control Act of 1976 ([Labor Code §§ 9000 et seq.](#))

## IMPLEMENTING REGULATIONS

[California Code of Regulations Industrial Relations Title 8 Section 5203 et seq.](#)

## PURPOSE

To establish requirements for use of regulated chemicals which can be carcinogenic.

## SUMMARY

This code sets forth standards for use of specific chemicals which can be carcinogenic. It establishes procedures for implementation of the code and for inspections to verify enforcement. It gives penalties for violations and lists regulated chemicals to which the code applies.

## APPLICABILITY

Use of specific regulated chemicals in California.

## LEAD AGENCY

[Division of Occupational Safety and Health--Department of Industrial Relations](#)

## UNIVERSITY RESPONSIBILITY

The EH&S Office regulates the use of carcinogens on campus and in laboratories in accordance with State requirements and campus policies.

LBNL follows [DOE Orders](#) for regulating the use of carcinogens.

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## **EXTERNAL REQUIREMENTS--STATE**

3-S04 California Radiation Control Law ([Health and Safety Code §§ 1149600 et seq.](#))

### IMPLEMENTATION REGULATIONS

[CCR Title 17 Public Health §§30100 et seq.](#)

### PURPOSE

To control the use and disposal of radioactive material and radiation-producing machines.

### SUMMARY

This code sets standards for enforcement and requirements for use, storage, transportation, and disposal of radioactive material. It requires the licensing and registration of radioactive materials and radiation-producing machines.

### APPLICABILITY

Possession and use of radioactive materials and radiation-producing machines in California.

### LEAD AGENCY

[Department of Public Health Radiologic Health Branch](#)

### UNIVERSITY RESPONSIBILITY

The EH&S Radiation Safety Officer and the Radiation Safety Committee are responsible for authorization, control, distribution, use and disposal of radioactive materials and radiation-producing machines.

LBNL follows DOE Orders on Requirements for Radiation Protection.

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## **EXTERNAL REQUIREMENTS--STATE**

3-S05 Uniform Controlled Substances Act ([Health and Safety Codes §§11000 et seq.](#))

### IMPLEMENTING REGULATIONS

[CCR Title 11 Attorney General §§800 et seq.](#)

## PURPOSE

To regulate acquisition and use of narcotics and dangerous drugs.

## SUMMARY

This Act supplements the Federal Controlled Substances Act, governing the acquisition and use of controlled substances within the State. The Code sets forth regulations for human subject research with controlled substances. [Health and Safety Code Section 11213](#) gives authority to the State Research Advisory Panel, established under Sections 11480 and 11481, to approve the use of controlled substances in research, instruction, and analysis.

### [State of California Research Advisory Panel](#)

Anyone planning to conduct research in the following areas must submit a research application to the State Research Advisory Panel:

1. Any research involving any Schedule 1 controlled substance; or
2. Human research utilizing any Schedule I or Schedule II controlled substance except those included in subsection d of Schedule II; (See *C & G Manual Chapter 18* for general information on human subjects review and approval); or
3. Research for treatment of drug abuse utilizing any scheduled or unscheduled drug.

The Schedules of Controlled Substances are explained in [Section 3-F04](#).

It is unlawful to engage in any of the above described research areas without prior authorization from the Research Advisory Panel. [Application requirements and guidelines](#) are available from their website.

## APPLICABILITY

Use of scheduled substances in the State of California.

## LEAD AGENCY

[State Department of Justice – Office of the Attorney General](#)

## UNIVERSITY RESPONSIBILITY

The University procedures for the acquisition and use of controlled substances are established *Business and Finance Bulletin* [BUS-50, Controlled Substances Program](#). Under [BUS-50](#), Materiel Management and Purchasing Offices are responsible for authorizing applications for registration, official order forms, and reporting requirements. (See Section [3-610](#).)

Any University Principal Investigator intending to conduct research in the areas covered by the State Research Advisory Panel described above must submit a research application to the Panel.

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## **EXTERNAL REQUIREMENTS--STATE**

3-S06 Public Works and Purchases ([Government Code §§4475 et seq.](#))

### **PURPOSE**

To prohibit State agencies from contracting with entities which are in violation of State or federal water or air pollution laws.

### **SUMMARY**

No State agency can enter into any contract with any person or entity in violation of any order of the [State Air Resources Board](#) or in violation of waste discharge requirements in the [Water Code](#) or in violation of provisions of federal laws relating to air and water pollution.

### **APPLICABILITY**

Any State agency including the University.

### **LEAD AGENCY**

[State Air Resources](#) and [Water Resources Control Boards](#)

### **UNIVERSITY RESPONSIBILITY**

Material Managers shall take precautions to insure that the University does not enter into contracts with any person or entity on the list of violators, the [Federal Excluded Parties List](#). *Business and Finance Bulletin BUS-56*, Material Management: Purchases from Entities Violating State or Federal Water or Air Pollution Laws contains more details on this subject.